

THE LOS ALAMOS YMP ORGANIZATION AND QUALITY PROGRAM DESCRIPTION

LOS ALAMOS QUALITY PROGRAM



APPROVAL FOR RELEASE

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Los Alamos
Yucca Mountain Site
Characterization Project

HISTORY OF REVISIONS

REVISION NO.	EFFECTIVE DATE	PAGES REVISED	REASON FOR CHANGE
R0	01/31/94	N/A	Initial procedure.
R1	07/13/94	All	Revised to address QARD requirements
R2	11/03/94	4, 5, & Att. 2	Revised to clarify QARD requirements.
R3	07/31/95	3, 5, 8, Atts. 1 & 2	Revised to update references (editorial changes only).
R4	07/16/96	3-5, Atts. 1,& 2	Minor, non-substantive editorial changes, to clarify design control requirements, assessment and interface responsibilities, and procedure use requirements.
R5	06/02/97	All	Revised to address the new Technical Assurance group and Office of Quality Assurance representative responsibilities.

Los Alamos

Yucca Mountain Site

Characterization Project

THE LOS ALAMOS YMP ORGANIZATION AND QUALITY PROGRAM DESCRIPTION

1.0 PURPOSE

This procedure describes the organizational structure and quality assurance program of the Los Alamos National Laboratory (Los Alamos) Yucca Mountain Site Characterization Project (YMP or Project). It also describes the process to revise the Los Alamos YMP organizational structure.

2.0 SCOPE

2.1 This procedure governs Los Alamos YMP organizational activities.

2.2 This procedure applies to Los Alamos and Los Alamos-subcontractor personnel (hereafter referred to as YMP personnel) who work under the Los Alamos YMP quality assurance program.

3.0 REFERENCES

DOE/RW-0333P, Office of Civilian Radioactive Waste Management Quality Assurance Requirements and Description (QARD)
LANL-YMP-QP-04.6, Procurement

4.0 DEFINITIONS

4.1 Affected Organization

An affected organization (Los Alamos) is an organization performing YMP work subject to QARD requirements. At Los Alamos there are four organizations: Administration and Control; Technical Assurance; Site and Regulatory; and Test Coordination Office. Any YMP personnel working to a Los Alamos YMP job title and working under Los Alamos YMP Quality Program are considered part of Los Alamos YMP regardless of physical location of personnel.

4.2 Interface

An interface occurs when YMP personnel request the exchange of technical work or information that requires control (under QARD requirements) from another Yucca Mountain Project Participant. Interfaces are documented by a method commensurate with their level of complexity and importance.

5.0 RESPONSIBILITIES

YMP personnel who conduct activities governed by the Los Alamos YMP quality assurance program are responsible for activities identified in Section 6.0 of this procedure.

6.0 PROCEDURE

The use of this procedure must be controlled as follows:

- If this procedure cannot be implemented as written, Los Alamos YMP personnel should notify appropriate supervision. If it is determined that a portion of the work cannot be accomplished as described in this QP, or would result in an undesirable situation, that portion of the work will be stopped and not resumed until this procedure is modified or replaced by a new document that reflects the current work practice.
- YMP personnel may use copies of this procedure printed from the controlled document electronic file; however, YMP personnel are responsible for assuring that the correct revision of this procedure is used.
- When this procedure becomes obsolete or superseded, it must be destroyed or marked “superseded” to ensure that this document is not used to perform work.

6.1 Los Alamos YMP Organization Structure

The **Laboratory Lead** (LL) manages the Los Alamos YMP and is responsible for all management activities designed to achieve and maintain quality. The Los Alamos YMP Organization Description, Attachment 1, describes the generic organizational structure, authority, and responsibility of Los Alamos YMP personnel.

6.2 Los Alamos YMP Quality Assurance Program Description

The Los Alamos YMP Quality Assurance Program Description, Attachment 2, contains a policy statement and a program overview. The policy statement, approved and signed by the LL, describes the context in which the quality assurance program was created and defines YMP personnel responsibility to the program. The program overview summarizes the QARD criteria that governs the quality assurance program and references the applicable documents that implement the QARD criteria.

6.3 Interface Control

- 6.3.1 Internal interfaces are established and controlled by Los Alamos Quality Administrative Procedures (QP).
- 6.3.2 External interfaces for work conducted in support of the Los Alamos YMP in which the work or task is assigned through the procurement process are controlled in accordance with applicable QPs and the procurement process addressed in QP-04.6. External interfaces with DOE and other YMP participants are controlled according to appropriate YMP procedures.

7.0 RECORDS

The following record may result from this procedure

- Documentation delegating signature authority, as appropriate.

8.0 TRAINING REQUIREMENTS

8.1 YMP personnel who conduct activities governed by the Los Alamos YMP quality assurance program are required to train to this procedure. Training is accomplished as “read only.” YMP personnel may also need to train to applicable Project Office procedures.

8.2 Training to this procedure by limited-function YMP personnel is determined by the appropriate Los Alamos YMP supervisor on a case-by-case basis.

9.0 ATTACHMENTS

Attachment 1: Los Alamos YMP Organization Description (5 pages)

Attachment 2: Los Alamos YMP Quality Assurance Program Description (6 pages)

Los Alamos YMP Organization Description

A. Organizational Structure

The Los Alamos YMP is directed and managed by the Laboratory Lead (LL). The LL reports to the Management and Operations (M&O) contractor, TRW.

The YMP at Los Alamos is divided into four organizations: Site and Regulatory Investigations, Test Coordination Office, Administration and Control, and Technical Assurance. The Test Coordination Office (located in Las Vegas, NV) is administered and led by the Deputy LL. The Exploratory Studies Facility (ESF) Engineering Support Project Leader, Test Planning and Design Project Leader and Field Test Coordination Project Leader report to the Deputy LL. Other organizations are led by a Project Leader who report directly to the LL.

Additional management positions are Functional Coordinators and Principal Investigators. Functional Coordinators (e.g., Technical Coordinator) report to a Project Leader. Principal Investigators, who conduct the majority of technical work, may report to a Functional Coordinator, Project Leader, or the LL.

The LL, Deputy LL, Project Leaders, Functional Coordinators, and Principal Investigators constitute the Los Alamos YMP management. The lines of communication and generic reporting relationships are depicted in Figure 1.

The Los Alamos YMP management has total responsibility for meeting quality requirements. All YMP personnel are responsible for the quality of their own work. The Office of Quality Assurance (OQA) representative is responsible for the verification of quality.

The LL is responsible for the quality assurance program. The LL ensures the development, implementation, and self assessment of the quality assurance program and retains ultimate review and approval authority on matters pertaining to the implementation of quality assurance program requirements.

The Los Alamos YMP organization structure includes all Los Alamos and Los Alamos sub-contractor personnel who perform work governed by Los Alamos YMP quality assurance program requirements regardless of organizational affiliation. With this structure, there is no organizational interface since these individuals work directly for Los Alamos YMP and take direction from the Los Alamos LL. Project Office support that is coordinated through the Office of Quality Assurance and the Test Coordination Office and is controlled through project procedures, is not an interface as defined herein.

B. Functional Title

The specific duties and responsibilities of YMP personnel are described in position descriptions. The following functional titles are approved for use in position descriptions of the Los Alamos YMP:

Laboratory Lead
Deputy Laboratory Lead

Project Scientist
Project Leader
Deputy Project Leader
Functional Coordinator (e.g., Technical Coordinator)
Functional Liaison (e.g., Technical Assurance Liaison)
Functional Specialist (e.g., Technical Specialist)
Functional Advisor (e.g., Science Advisor)
Principal Investigator
Associate Investigator
Research Collaborator
Research Technician
Technical Assurance Engineer
Administrative Assistant

These titles are used to prepare position descriptions and organizational charts and to communicate organizational information. These titles are functional titles and a position description title should be added to a title to be more job specific, e.g., Associate Investigator for Hydrology. Changes to these generic titles or creation of new generic titles must be approved by the LL through a revision of this procedure. The generic reporting relationship of these positions is shown in Figure 1.

C. Functional Responsibilities for Quality and Generic Responsibilities

Quality is achieved and maintained through compliance with implementing procedures by those YMP personnel who have been assigned responsibility for performing the work. Listed below are the YMP managers responsible for achieving and maintaining quality (their generic duties are also listed):

Laboratory Lead: Has ultimate responsibility for the establishment and execution of the quality assurance program; however, the LL delegates work through implementing procedures. Responsibilities include approving implementing procedures and technical information products. The LL is also responsible for the overall management of the Los Alamos YMP. Consequently, the LL makes management assignments to affected organizations as appropriate. A Deputy LL, based in Las Vegas, NV is responsible for daily interactions with the DOE and supervises Test Coordination Office activities.

Project Leaders and Functional Coordinators: Responsible for implementing the quality assurance program in their areas of responsibility on a day-to-day basis. These responsibilities include developing procedures, participating in audits and surveillances, reviewing technical information products, and ensuring that their support staff is trained to the appropriate procedures.

The Site and Regulatory Investigations Project Leader is responsible for integrating and coordinating all Los Alamos scientific-related activities being conducted by Los Alamos YMP principal investigators and other YMP organizations. The Administration and Control Project Leader is responsible for administrative and business management activities. The Test Planning and Design, Field Test Coordination, and ESF Engineering Support Project Leaders, who report directly to the Deputy LL, are responsible for all TCO activities. Coordinators are responsible for selected areas of expertise (e.g., Training Coordinator).

Principal Investigators: Responsible for understanding and implementing the quality assurance program for scientific investigation activities, as applicable, on a day-to-day basis. These responsibilities include developing procedures as appropriate, participating in audits and surveillances, and ensuring that their support staff is trained to the appropriate procedures. Principal investigators are also responsible for technical competence (e.g., planning and documenting scientific investigations, collecting samples, generating and interpreting data, etc.).

D. Dedicated Technical Assurance Positions

Technical Assurance Project Leader (TAPL): This position, occupied by an individual with the appropriate knowledge and experience in management and quality assurance, will be at the same or higher organizational level as the highest line manager (Project Leader) directly responsible for performing work. The TAPL will have access to the appropriate levels of management to cause decisions to be made in a timely manner.

The **TAPL** will provide technical assurance (TA) support for science via the TA organization. This support is comprised of the following functions:

Review of Products

The TA organization will perform in-line reviews of technical products such as: technical information products; study plans; reports; data packages; procurements; field work packages; milestones; deliverables; etc. against criteria stated in the appropriate procedures and other governing documents. These reviews will provide assurance to the line organizations that the products comply with Project Office and M&O requirements.

Support to Line for Implementation

TA will provide support in the following areas: M&TE control; sample management; field work packages; facilitate/develop deficiency responses; QA orientation; preplanning activities (grading); etc. TA will work as an integral part of the line organization to help identify and resolve issues/concerns before they become problems. As directed by Los Alamos management, TA will perform self assessments of science activities during data collection, document development, and test performance, providing feedback to management with respect to compliance to Los Alamos' program and the quality of products. Additionally, TA will help monitor activities which involve multiple locations/entities to ensure consistency and coordination between them.

Software Review and Configuration Management

TA will provide in-line reviews of software products to ensure they are developed and used in accordance with Los Alamos procedures and that the codes are acceptable for use in quality-affecting products.

Maintain Local Program

TA will provide support for the development and maintenance of procedures necessary to support the work activities.

Technical Assurance Liaison: Facilitates implementation of the Los Alamos YMP quality assurance program for selected divisions, groups, or units. Reports to the TAPL.

E. Quality Assurance Management

The Director, OQA, Office of Civilian Radioactive Waste Management (OCRWM), U.S. Department of Energy is responsible for YMP quality assurance functions. The responsibilities and reporting hierarchy of the OCRWM OQA are identified in OCRWM QAP 1.1, Organization.

Whenever the term Quality Assurance Project leader (QAPL), Quality Assurance representative, Quality Assurance Liaison (QAL), or similar term is used in Los Alamos implementing documents, it will be deemed to mean the OCRWM OQA representative. Los Alamos implementing procedures will incorporate the roles and responsibilities of the OCRWM OQA (OQA representative) at the next revision of the procedure.

OQA will provide quality assurance (QA) support. This support is comprised of the following functions: audits; surveillances; corrective action acceptance and verification; implementing document reviews; non-conformance acceptance and verification; trending; requirements matrix review; procurement document reviews; source evaluation; and maintenance of the qualified suppliers list (QSL).

F. Delegation of Work

YMP personnel may delegate signature authority to other positions within their organization for actions required by implementing documents. However, the individual delegating authority retains responsibility for the work. Such signature authority is documented (e.g., by memorandum, letter, or Position Description generated by QP-02.5) and submitted as a quality assurance record in accordance with QP-17.6.

YMP PERSONNEL GENERIC REPORTING RELATIONSHIPS

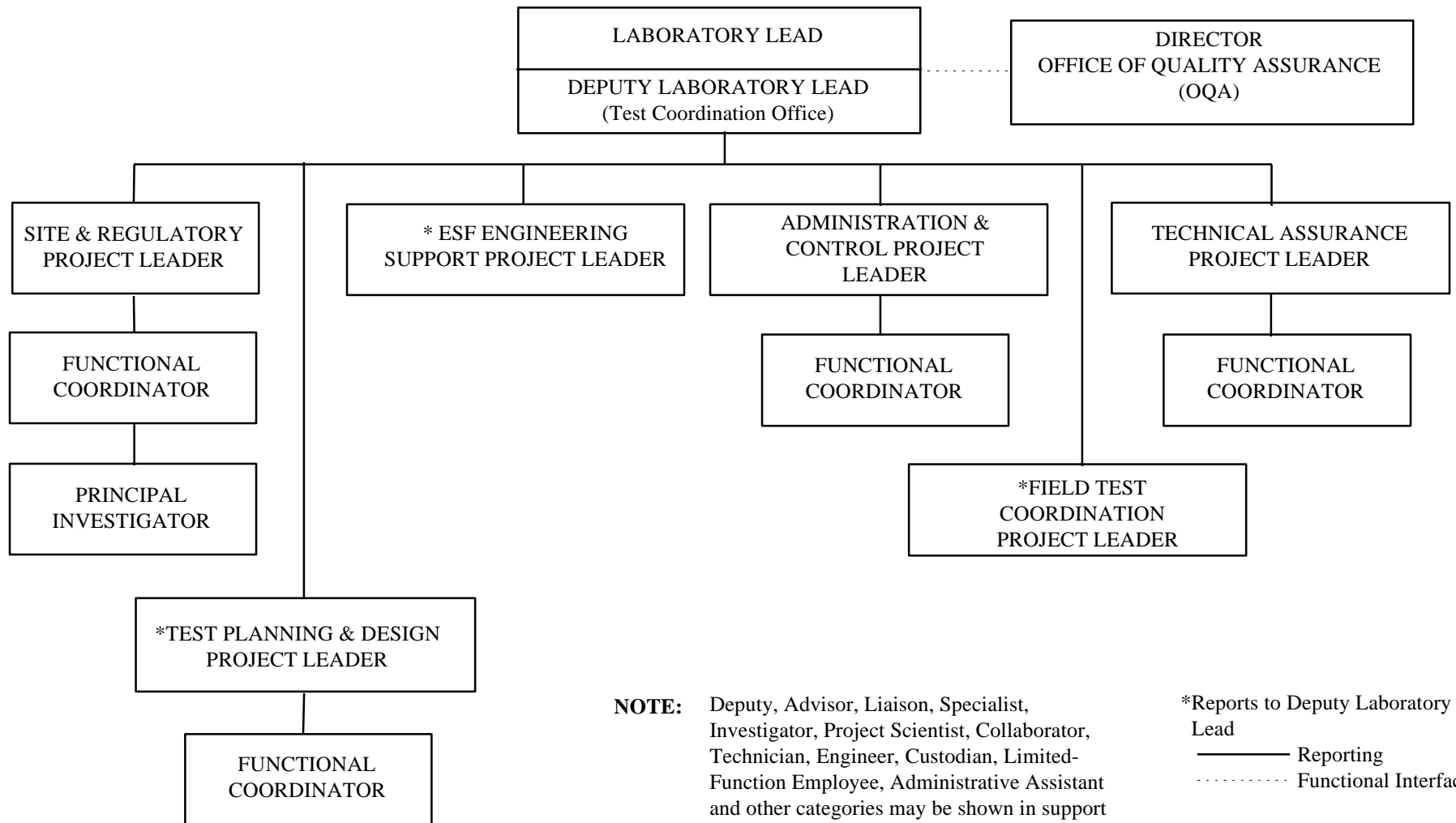


Figure 1

Los Alamos YMP Quality Assurance Program Description

I. Policy Statement

The U.S. Department of Energy (DOE) is authorized by the Nuclear Waste Policy Act, as amended in 1987, to perform site characterization, obtain a license, construct a facility, and safely operate a geologic repository. The act established the Office of Civilian Radioactive Waste Management (OCRWM) within the DOE to carry out this mission. Central to this mission is protecting the health and safety of the public and workers and the quality of the environment. As a Program Participant, Los Alamos National Laboratory (Los Alamos) is committed to the highest standards of technical excellence in support of the OCRWM and its mission. The Los Alamos YMP quality assurance program provides documentation that Los Alamos personnel are performing at this high level.

Los Alamos meets this commitment through the implementation of a quality assurance program that implements applicable requirements stated in the DOE/RW-0333P Quality Assurance Requirements and Description (QARD). Implementation of QARD requirements is accomplished through procedures that describe various activities. The quality assurance program applies to site characterization data and samples and to activities that provide data used to assess the potential dispersion of radioactive materials from a licensed facility. The quality assurance program also applies to activities related to sample collection and to collection and analysis of data that supports performance confirmation or performance assessment.

All Los Alamos Yucca Mountain Site Characterization Project personnel performing activities governed by the QARD will be oriented to applicable concepts and requirements of the quality assurance program. Activities governed by the QARD will be planned and performed in accordance with applicable implementing procedures and compliance with the quality assurance program is mandatory.

Gilles Y. Bussod
Los Alamos Laboratory Lead

Date

II. Program Overview

A. Description

The DOE/RW-0333P Quality Assurance Requirements and Description (QARD) is the principal quality assurance document for the Civilian Radioactive Waste Management Program. The QARD establishes the minimum regulatory requirements and program commitments necessary for the development of an effective quality assurance program. Documents that implement the quality assurance program translate the QARD requirements into work processes. These implementing documents are designed to meet the needs of the Los Alamos YMP such that management processes will be carried out efficiently and effectively.

Los Alamos implementing documents are either quality administrative procedures (QP) or detailed technical procedures (DP). The type of document chosen to control work will be appropriate to the nature and circumstances of the work being performed. The QPs identify requirements and provide administrative controls, whereas DPs provide technical requirements and controls. These documents ensure that standard practice and objective evidence (i.e., records) attest to compliance with QARD requirements and provide the methods for both achievement and verification of quality. Copies of implementing documents are available via the EES-13 HomePage or through the Document Control Coordinator.

The Los Alamos implementing documents that meet applicable QARD requirements are identified in the Requirements Traceability Matrix (RTM).

B. QARD Elements Applicable to Los Alamos YMP

This section identifies those elements in the QARD that are applicable to the Los Alamos YMP quality assurance program. Applicable Los Alamos QPs and Project Office procedures may be listed.

1.0 Organization

This criterion requires the Los Alamos YMP to maintain an organizational structure that allows implementation of the QARD. This requirement includes describing organizational responsibilities and internal and external interfaces. The basis of this criterion is that quality is achieved and maintained by those assigned responsibility for performing work.

- YAP-3.6Q, Physical Interface Control
- LANL-YMP-QP-01.3, Conflict Resolution
- LANL-YMP-QP-01.4, The Los Alamos YMP Organization and Quality Program Description

2.0 Quality Assurance Program

This criterion requires the Los Alamos YMP to plan, implement, and maintain a quality assurance program. It also requires that programs be

developed for the evaluation, selection, indoctrination, training, and qualification of appropriate personnel. This element includes document review requirements and surveys. The basis for this criterion is to identify those personnel who are required to follow the quality assurance program. This criterion is met by implementing this procedure (see Policy Statement).

- LANL-YMP-QP-02.5, Selection of Personnel
- LANL-YMP-QP-02.7, Personnel Training
- LANL-YMP-QP-02.11, Personnel Orientation
- LANL-YMP-QP-02.12, Exemption Control
- LANL-YMP-QP-02.15, Requirements Traceability
- LANL-YMP-QP-03.23, Preparation and Review of Technical Information Products and Study Plans
- LANL-YMP-QP-06.2, Preparation, Review, and Approval of Quality Administrative Procedures
- LANL-YMP-QP-06.3, Preparation, Review, and Approval of Detailed Technical Procedures

3.0 Design Control

This criterion provides requirements to ensure that designs are defined, controlled and verified. Although not specifically responsible for YMP design control, Los Alamos YMP Test Coordination Office coordinates design activities by reviewing applicable test requirements and specifications to ensure that they are correctly submitted to the design organization for incorporation into the final structure, as per this criterion.

- YAP-3.4Q, Field Change Control Process
- YAP-5.7Q, ESF Testing Field Work Packages
- LANL-YMP-QP-03.25, Review of Design and Test-Related Information

4.0 Procurement & 7.0 Control of Purchased Items and Services

These criteria require the Los Alamos YMP to purchase items and obtain services according to QARD specifications. The basis for these criteria is to ensure that the proper items and services are provided.

- LANL-YMP-QP-04.6, Procurement

5.0 Implementing Documents & 6.0 Document Control

These criteria require the Los Alamos YMP to perform all quality-affecting activities according to controlled implementing documents.

- YAP-6.2Q, Distribution, Maintenance, and Use of Controlled and Managed Documents
- LANL-YMP-QP-06.1, Document Control

- LANL-YMP-QP-06.2, Preparation, Review, and Approval of Quality Administrative Procedures
- LANL-YMP-QP-06.3, Preparation, Review, and Approval of Detailed Technical Procedures

12.0 Control of Measuring and Test Equipment

This criterion requires the Los Alamos YMP to calibrate and control all measuring and test equipment including appropriate standards, according to QARD specifications.

- LANL-YMP-QP-12.3, Control of Measuring and Test Equipment and Standards

16.0 Corrective Actions & 18.0 Audits

These criteria require that audits be conducted of the Los Alamos YMP according to QARD specifications. These criteria are designed to ensure that the applicable QARD requirements are being met and quality is achieved. Audits, vendor qualification and surveillances will be conducted by DOE. The Los Alamos YMP follows Project Office procedures with respect to issuing formal deficiencies.

- AP-16.1Q, Performance/Deficiency Reporting
- AP-16.2Q, Corrective Action and Stop Work
- AP-16.3Q, Trend Evaluation and Reporting

17.0 Quality Assurance Records

This criterion requires the Los Alamos YMP to capture all quality assurance records in a records system. This criterion will prevent the loss of records by establishing a dual storage system.

- LANL-YMP-QP-17.6, Records Management

Supplement I: Software

This criterion requires the Los Alamos YMP to develop, acquire, control, and use scientific and engineering software according to QARD specifications.

- LANL-YMP-QP-03.20, Software Configuration Management
- LANL-YMP-QP-03.21, Software Life Cycle

Supplement II: Sample Control

This criterion requires the Los Alamos YMP to control all samples. Samples must be traceable from “cradle to grave.”

- LANL-YMP-QP-08.1, Identification and Control of Samples

- YAP-15.1Q, Control of Nonconformances
- YAP-SII.1Q, Submittal, Review, and Approval of Requests for Yucca Mountain Site Characterization Project Geologic Specimens
- YAP-SII.2Q, Requesting Samples for Examination at Yucca Mountain Site Characterization Project Sample Management Facility
- YAP-SII.4Q, The Collection, Submission, and Documentation of Non-core and Non-cuttings Samples to the Sample Management Facility Site Characterization

Supplement III: Scientific Investigation

This criterion requires the Los Alamos YMP to perform all scientific investigations according to the scientific notebook method or the applicable DP or a combination of both. All scientific investigations must be planned and the data from these investigations must be traceable to their source. Unqualified data relied upon to address safety and waste isolation issues may be used in scientific investigation provided traceability to its status as unqualified data is maintained. Unqualified data requiring qualification, will be qualified at appropriate times in accordance with YAP-SIII.1Q.

- LANL-YMP-QP-03.5, Documenting Scientific Investigations
- LANL-YMP-QP-03.23, Preparation and Review of Technical Information Products and Study Plans
- LANL-YMP-QP-08.3, Transfer of Data
- YAP-2.2Q, Preparation, Review, Approval, and Revision of Site Characterization Plan Study Plans
- YAP-30.12, Publications Review, Approval and Distribution
- YAP-SIII.1Q, Qualification of Unqualified Data
- YAP-SIII.3Q, Control and Transfer of Technical Data on the Yucca Mountain Site Characterization Project

C. Conformance To DOE Order 5700.6C

Los Alamos policy requires that Laboratory programs identify how they comply with DOE Order 5700.6C, and 10 CFR 830.120. Although the YMP is exempt from these requirements, the QARD does meet the basic elements of 5700.6C (see Table 1).

REQUIREMENTS MATRIX
DOE/RW-0333P QARD VERSUS
DOE ORDER 5700.6C

DOE/RW-0333P QARD, R5	DOE Order 5700.6C Basic Elements									
	1	2	3	4	5	6	7	8	9	10
1.0 Organization	X									
2.0 Quality Assurance Plan	X	X							X	
3.0 Design Control						X				
4.0 Procurement Document Control							X			
5.0 Implementing Documents				X						
6.0 Document Control				X						
7.0 Control of Purchased Items/Service							X			
8.0 Identification & Control of Items					NOT APPLICABLE					
9.0 Control of Special Processes					NOT APPLICABLE					
10.0 Inspection					NOT APPLICABLE					
11.0 Test Control					NOT APPLICABLE					
12.0 Measuring & Test Equipment					X			X		
13.0 Handling, Storage, & Shipping					NOT APPLICABLE					
14.0 Inspection, Test & Operating Status					NOT APPLICABLE					
15.0 Nonconformances					NOT APPLICABLE					
16.0 Corrective Action			X						X	
17.0 Quality Assurance Records				X						
18.0 Audits									X	X
Supplement I Software					X					
Supplement II Sample Control					X					
Supplement III Scientific Investigation					X					
Supplement IV Field Surveying					NOT APPLICABLE					
DOE Order 5700.6C Basic Elements										
1. Program						6. Design				
2. Personnel Training and Qualification						7. Procurement				
3. Quality Improvement						8. Inspection Testing				
4. Document and Records						9. Self Assessment				
5. Work Processes						10. Independent Verification				

Table 1